

January 29, 1999

MEMORANDUM

SUBJECT: Dimethoate (035001), Response to Novigen Acute Probabilistic (Monte-Carlo) Dietary Exposure Analysis. DP Barcode D249135. No MRID. Rereg. Case No. 2675

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Cheminova Agro A/S (Cheminova) has submitted a Monte Carlo (Tier III) acute dietary risk assessment for dimethoate. The analysis was conducted by Novigen. CEB1 has been asked to review this submission.

Background

The EPA conducted a Tier 1 assessment of acute dietary risk for dimethoate using the Dietary Risk Evaluation System, DRES, (Brian Steinwand, memo to Mike Metzger, March 1997). Tier 1 acute dietary risk analysis is based on high end exposures derived from existing tolerances, assuming 100% tolerance level, and 100% crop treated. Some modest adjustments (decreasing the turnip root tolerance from 2 to 0.02 ppm, and the deletion of lentils) did not impact the analysis. The Margin of Exposure (MOE) values (all below 40) indicated a concern, given that an acceptable MOE is 100 or greater.

A limited Tier 2 analysis was conducted in HED to refine the DRES assessment and to try to determine which commodity(ies) pose the highest exposure estimates. HED was not able to make this determination using DRES system. In addition, rerunning the DRES analysis using acute anticipated residues (AR) was not expected to mitigate the acute dietary risk. It was therefore recommended that the registrant(s) conduct a probabilistic (Monte Carlo) analysis to address acute dietary concerns.

The acute dietary toxicological dose (oral NOAEL) for dimethoate was previously selected at 2.0 mg/kg/day based on absence of pupil response in rats. However, in the recent decision (7/7/98) by the Hazard Identification Assessment Review Committee (HIARC) this value was lowered to 0.06 mg/kg/day due to the lack of confidence in the previous endpoint selected and lack of measurement of cholinesterase inhibition in that study. The new endpoint was selected from a subchronic neurotoxicity study in which cholinesterase inhibition was measured. The HIARC also recommended that this new NOAEL be used for acute dietary risk assessment until a new acute neurotoxicity study in which cholinesterase inhibition is measured is conducted. In addition, HIARC recommended that a 10X uncertainty factor for enhanced susceptibility of sensitive subpopulation be removed based on weight-of-the-evidence consideration. The acceptable MOEs for acute dietary risk assessment for dimethoate are >100 (10X uncertainty factor for inter and 10X uncertainty factor for intraspecies). Tolerances are established for total residues of the insecticide dimethoate and its oxygen analog omethoate (40 CFR 180.204).

The Agency requested in a letter to Cheminova (Layne, 1997) that a Monte Carlo dietary exposure and risk assessment be conducted. In response, Cheminova submitted a Monte Carlo study report (conducted by Novigen Sciences, Inc.) which is reviewed in this memorandum. In addition, in an attachment to the report, Cheminova contested the decision by HIARC to lower the NOAEL from 2.0 mg/kg/day to 0.06 mg/kg/day and used the old NOAEL value (2.0 mg/kg/day) in their assessment.

Conclusions

In brief, the use of an outdated oral NOAEL, inappropriate exclusion of specific commodities in the analysis, inappropriate use of PDP data for non-blended and blended/mixed commodities, inappropriate assumption of residue concentration of zero for omethoate when it was not analyzed in PDP data, and lack of hard copy were the major deficiencies of the submission which rendered it unacceptable. Even with certain inappropriate assumptions on the part of registrant and inadequacies in the submission, HED's recalculated margin of exposure (MOE) values based on the most recent NOAEL of 0.06 mg/kg/day (instead of earlier NOAEL of 2.0 mg/kg/day used by the registrant) ranged from 3-8 (MOE of >100 is required) at the 99.9th percentile; thus, exposure exceed HED's levels of concern. The deficiencies are described below in more detail:

- 1- The EPA-accepted NOAEL of 0.06 mg/kg/day should have been used in the analysis instead of

the 2 mg/kg/day used by the registrant. The Agency has concluded that until an acute neurotoxicity study in which cholinesterase inhibition is measured is submitted, the NOAEL of 0.06 mg/kg/day should be used in acute dietary risk assessments.

2- Use of monitoring data from USDA's Pesticide Data Program (PDP) for non-blended commodities in acute dietary risk assessments is not currently acceptable; therefore, in the absence of adequate field trial data for relevant commodities, tolerance-level residues should be used in the analysis.

3- The registrant's analysis conducted using the Dietary Exposure Evaluation Model (DEEM) did not include in the analysis asparagus and brussels sprouts which were supported through reregistration in the RED document and should therefore have been included. The analysis also used an application rate of 0.16 lb a.i./A instead of 0.25 lb a.i./A as the maximum seasonal rate for peas. Future analysis should include all the commodities supported through reregistration, with field trial residues generated at maximum label rates. The Agency emphasizes that provided the labels have not been changed or the registered sites (i.e. recommended in the RED chapter) have not been formally dropped, the existing labels and registered sites continue to be the source of information for dietary risk assessments.

4- The registrant's proposal for use of "non-detect" or "not-analyzed" residue data for dimethoate and omethoate in the acute dietary exposure assessment is not acceptable. The registrant's proposal and the EPA suggested treatment of the data is presented below:

<i>Dimethoate Value Reported</i>	<i>Omethoate Value Reported</i>	<i>Total Residue Value Used in the Cheminova Assessment</i>	<i>EPA Suggested Treatment</i>
<i>Non-Detect</i>	<i>Detect</i>	<i>Full LOD for Dimethoate for that sample + Omethoate Detect</i>	<i>1/2 LOD for Dimethoate for that sample + Omethoate Detect</i>
<i>Non-Detect</i>	<i>Non-Detect</i>	<i>1/2 the average LOD for Dimethoate for that commodity + 1/2 the average LOD for Omethoate for that commodity</i>	<i>1/2 LOD for Dimethoate for that sample + 1/2 LOD for Omethoate for that sample</i>
<i>Detect</i>	<i>Not analyzed</i>	<i>Detect for Dimethoate + zero for Omethoate</i>	<i>Detect for Dimethoate + Detect (same value) for Omethoate</i>
<i>Non-Detect</i>	<i>Not analyzed</i>	<i>1/2 the average LOD for Dimethoate for that commodity + zero for Omethoate</i>	<i>1/2 LOD for Dimethoate for that sample + 1/2 the average LOD for Omethoate for that commodity</i>

5- The submission lacks hard copy of input data files for all the commodities except apples. Hard copy and electronic copy of input data files should accompany the analysis report in accordance with the "Guidance for Submission of Probabilistic Exposure Assessments to the Office of Pesticide Programs Health Effects Division".

6- Appropriate procedure was not followed for blended processed commodities. For this type of commodity, a point estimate (resulting from average field trial residue or average monitoring data after incorporating 1/2 LOD values for non-detect and incorporating % crop treated (%CT) as a residue adjustment factor and correcting for processing factor) should have been used in the analysis instead of a residue data file.

7- Values for % CT should not have been incorporated into PDP data for blended commodities such as wheat, soybean, and dry beans.

8- The registrant use of PDP monitoring data and BEAD %CT estimates as surrogate data for five crops¹ is not acceptable since those crops are considered to be non-blended commodities; PDP monitoring data can not be used for non-blended commodities.

Recommendations

CEB1 recommends that the analysis be repeated with all the corrections listed in conclusion items 1-8. In addition, the more recent BEAD report (Sept. 1998) for %CT should be used in the next analysis. The new %CT information is incorporated into this review.

Detailed Considerations

Data and values used in the analysis:

- Food consumption data from the 1989 through 1992 USDA Continuing Survey of Food Intake by Individuals (CSFII) (USDA HNIS, 1992, 1993, 1994)
- Residue data:
 - monitoring data from USDA's Pesticide Data Program (PDP) (calendar years 1994-1996); [Note: because of unavailability of PDP data for all crops, PDP data were translated to some crops in the smaller crop subgroups.
 - field trial data (sorghum and succulent peas only); and
 - tolerance-level residues when neither of the above sources were available
- %CT from BEAD's 1990-1994 report

Data Treatment:

¹ Broccoli was used for cauliflower, oranges were used for lemons, lettuce was used for endive (escarole), spinach was used for swiss chard, and apples were used for pears.

Tolerances are established for total residues of the insecticide dimethoate and its oxygen analog omethoate (40 CFR 180.204). Since not all of the PDP monitoring data had values for both residues, Novigen followed a set of rules for six scenarios of “non-detect” or “not-analyzed” residues of dimethoate and/or omethoate under which the “non-detect” or “not-analyzed” residues were substituted with ½ LOD or LOD. Those scenarios, their treatments by Novigen, and recommended EPA procedures, where applicable, are listed in the following table.

Table 1- Novigen and EPA-recommended procedures for treatment of “non-detect” and “not-analyzed” PDP data.			
Dimethoate Value Reported	Omethoate Value Reported	Total Residue Value Used in the Cheminova Assessment	EPA Suggested Treatment
<i>Detect</i>	<i>Detect</i>	<i>Dimethoate detect + Omethoate Detect</i>	<i>no change</i>
<i>Detect</i>	<i>Non-Detect</i>	<i>Dimethoate Detect + ½ LOD for Omethoate for that sample</i>	<i>no change</i>
<i>Non-Detect</i>	<i>Detect</i>	<i>Full LOD for Dimethoate for that sample + Omethoate Detect</i>	<i>1/2 LOD for Dimethoate for that sample + Omethoate Detect</i>
<i>Non-Detect</i>	<i>Non-Detect</i>	<i>½ the average LOD for Dimethoate for that commodity + ½ the average LOD for Omethoate for that commodity</i>	<i>½ LOD for Dimethoate for that sample + ½ LOD for Omethoate for that sample</i>
<i>Detect</i>	<i>Not analyzed</i>	<i>Detect for Dimethoate + zero for Omethoate</i>	<i>Detect for Dimethoate + Detect (same value) for Omethoate¹</i>
<i>Non-Detect</i>	<i>Not analyzed</i>	<i>½ the average LOD for Dimethoate for that commodity + zero for Omethoate</i>	<i>½ LOD for Dimethoate for that sample + ½ the average LOD for Omethoate for that commodity¹</i>
<i>Not Analyzed</i>	<i>Detect or Non-Detect</i>	<i>Not applicable. There were no such cases.</i>	<i>no change</i>
<i>1. Review of some magnitude of residue studies shows that, contrary to what registrant contended, dimethoate residue levels are <u>not</u> “usually” found at levels 10 times higher than omethoate. We therefore conclude that substituting zero for omethoate residue level when it is “not analyzed” is not justified.</i>			

Novigen also derived individual sample residue distributions from PDP monitoring data (composite sample residue distribution) for single-serving risk assessments. The procedure is done by a statistical technique that is not currently approved.

Toxicological End Points, Margins of Exposure (MOE), and % Crop Treated (% CT)

In the Cheminova submission, the previous NOAEL of 2 mg/kg/day was used instead of the current EPA-accepted NOAEL of 0.06 mg/kg/day (set by HIARC, 7/7/1998); this is not acceptable and the MOE’s should be recalculated. HED recalculated margins of exposure (MOE’s), based on the revised NOAEL, all are below 100 (MOE of 100 or greater is required).

The following table only shows the resulting change in the MOE's based on the registrant reported exposure values and does not reflect the further adjustments that may be required. (See conclusions)

Table 2- Exposures and MOE's for the U.S. population and various population subgroups of concern reported by Cheminova.						
Subpopulation	Margin of Exposure					
	95th Percentile¹ (recalculated values)		99th Percentile¹ (recalculated values)		99.9th percentile¹ (recalculated values)	
	MOE	Exposure (mg / kg body wt./ day)	MOE	Exposure (mg / kg body wt./ day)	MOE	Exposure (mg / kg body wt./ day)
U.S. (all seasons)	1819 (55)	0.00110	499 (15)	0.00401	194 (6)	0.0103
Nursing infants (<1 yr)	5735 (172)	0.000349	803 (24)	0.00249	129 (4)	0.0155
Non-nursing infants	1702 (51)	0.00118	370 (11)	0.00541	137 (4)	0.0146
All infants (<1 yr)	1978 (59)	0.00101	418 (12)	0.00479	133 (4)	0.0150
Children (1-6 yrs)	1160 (34)	0.00172	293 (9)	0.00683	101 (3)	0.0198
Children (7-12 yrs)	1727 (52)	0.00116	456 (14)	0.00439	178 (5)	0.0112
Males (20+ yrs)	1891 (57)	0.00106	547 (16)	0.00366	250 (8)	0.00801
Females (13-50)	2566 (77)	0.000780	568 (17)	0.00352	213 (6)	0.00940
1. Values outside parenthesis represent MOE's reported by Cheminova using NOAEL of 2 mg/kg/day. Values inside parenthesis represent HED's recalculated MOE's based on the revised NOAEL of 0.06 mg/kg/day: <u>these do not incorporate other adjustments recommended by HED</u> and reflect the MOEs which would have been calculated by the registrant had the appropriate NOAEL of 0.06 mg/kg/day been used.						

The following table shows the comparisons of %CT values from BEAD 1990-4 (used by Novigen in the present submission) and the BEAD 1998 report. Any future submission on the part of the registrant should include the updated %CT data.

Table 3- Comparison of the new BEAD %CT (Sept. 1998) with the old values (1995) used in the Novigen's submission.

CROP	% Acres Treated (% crop treated)		
	BEAD's 1995 report; max values (used by Novigen)	BEAD's 98 Report	
		(Average)	(Maximum)
Apples	35	7.4	14.9
Beans (Dry)	5	3.8	7.0
Beans (Succulent)	15	13.3	19.6
Blueberries	85 ¹	-----	-----
Broccoli	30	28.8	37.9
Cabbage	25	16.9	24.8
Cantaloupes	10	10.5	12.7
Casabas	40 ²	24.4	48.8 ²
Cauliflower	30	22.4	38.4
Celery	5%	-----	-----
Cherries	10	5.7	8.7
Hot Pepper	4	3.0	10.4
Collard	30	25.4	40
Field Corn	1	0.4	0.7
Cottonseed	10	5.2	9.9
Endives / Lettuce	60	28.2	52.1
Grapefruits	10	4.3	8.5
Grapes, Grapes (wine)	10	6.5, 5.1	13, 11.4 ³
Kale	100	-----	-----
Lemons	35	25.4	58.4
Lentils	20 ⁴	-----	-----
Mustard Greens	100	-----	-----
Oranges	10	4.6	9.7
Pears	10	1.8	5.6

Table 3- Comparison of the new BEAD %CT (Sept. 1998) with the old values (1995) used in the Novigen's submission.

CROP	% Acres Treated (% crop treated)		
	BEAD's 1995 report; max values (used by Novigen)	BEAD's 98 Report	
		(Average)	(Maximum)
Pear Nectar	10	----	----
Peas, Green	20	26.8	56.8
Dry Peas	5	2.2	8.4
Peas, Green, Proc.	20	16.1	29.5
Pecans	20	11.6	19.4
Sweet Peppers	30	13.6	32.1
Potatoes	3	1.9	3.5
Safflower	25	18.7	41.1
Sorghum	1	0.7	1.3
Soybeans	1	-----	-----
Spinach	5	8.3	17.2
Tangerines	10 ⁵	10.8	21.9
Tomatoes (fresh), Tomatoes (proc.)	10	10.1, 28.4	18.3, 60
Turnips, Roots	100	-----	-----
Turnips, Tops	100	-----	-----
Watermelons	10	6.2	8.2
Wheat, Wheat (spring), Wheat (winter)	1	1.8, 0.3, 1.7	7.6, 0.7, 3.5
1. Based on % imported from Canada 2. Based on %CT for Melons, Honeydew 3. Grapes used for wine 4. Taken from peas, green since this was the highest BEAD %CT for peas. 5. Taken from the Orange % CT.			

Summary of residue data files (RDFs) submitted by Cheminova for each crop:

Brassica Leafy Vegetables

Broccoli and Cauliflower - Imputed PDP broccoli data (1994, 679 samples, 11 detects, min = 0.006 ppm and max = 0.036 ppm) were used. To match the expected 30% CT, 193 data points were added at 0.011 ppm (one-half LOD dimethoate plus one-half LOD omethoate). The DEEM default processing factor (PF) of 1 was used. These data were also translated to cauliflower since there were no field trial or PDP data for cauliflower.

EPA Response:

The procedure used is not acceptable. Using PDP monitoring data for non-blended commodities in dietary risk assessments is not acceptable; in the absence of field trial data for a commodity, tolerance-level residue values should be used with BEAD's current estimate of 38% CT.

Cabbage - The tolerance of 2 ppm and 25% CT was used² for cabbage, chinese celery/bok choy, cabbage-green and red, and cabbage-savoy.

EPA Response:

Rather than using the distribution of field trial data in its Monte-Carlo analysis, the registrant chose to use the tolerance (a point estimate) along with %CT. The Agency concurs with this approach. After further evaluation of the available magnitude of the residue data submitted to support of use on cabbage, the Agency deems them of little utility for the purposes of refining anticipated residue estimates. These data were generated from older field trials, conducted prior to the issuance of Subdivision O (or its 860 series successor), and were considered minimally acceptable for the purpose of reassessing the currently established tolerance for residues of dimethoate in/on cabbage. The data and data files used by the registrant for these commodities in the Monte Carlo (MC) analysis are acceptable.

Collards - The existing tolerance of 2 ppm and 30% CT were used.

EPA Response:

The Agency concurs with using the tolerance value rather than the old field trial data as discussed earlier (see comments for cabbage). The most recent BEAD report indicates 40% CT for collards, which should be incorporated in any future analysis.

² A reassessed tolerance for cabbage is to be determined (TBD). No additional field trial data are required to support the use of dimethoate on cabbage. The currently established tolerance for residues of dimethoate in/on cabbage will be reassessed once a label amendment to increase the PHI is submitted in order for the available data to support the currently established tolerance for dimethoate residue of concern in/on cabbage.

Kale - The tolerance of 2 ppm and 100% CT (no %CT data available) were used.

EPA Response:

The Agency concurs with using the tolerance value rather than the old field trial data as discussed earlier (see comments for cabbage).

Mustard Greens - The tolerance of 2 ppm and 100% CT (no %CT data available) were used.

EPA Response:

The Agency concurs with using the tolerance-level residue value rather than the old field trial data as discussed earlier (see comments for cabbage).

Cereal Grains

Field Corn - The corn grain tolerance of 0.1 ppm and 1% CT were used for corn grain, grain bran, grain endosperm, corn grain oil, corn sugar and corn sugar molasses. Processing factors (PF) of 0.14 (taken from corn starch) was used for corn grain oil, corn sugar and corn sugar molasses; a default PF of 1 was used for the rest.

EPA Response:

The procedure is not acceptable. Since corn *grain* is considered a blended commodity, one of the following procedures, depending on availability and appropriateness of data, should be applied in the MC analysis:

- use entire distribution of monitoring data, if available, for blended commodities with no further adjustment for %CT; use 1/2 LOD for all non-detects. The result is a RDF.

- or -

- use average of field trial data (see comments under cabbage for appropriate field trial data), incorporating a %CT as residue adjustment factor (i.e., multiplying by %CT); use 1/2 LOD for non-detects. The result should be entered into the exposure analysis as a point estimate. The tolerance-level residue value should be used in the absence of average field trial data.

Since corn *bran*, corn *endosperm*, corn *grain oil*, corn *sugar*, and corn sugar *molasses* are blended processed commodities, one of the following procedures, depending on

availability and appropriateness of data, should be applied for these commodities:

- use average of field trial data (see comments under cabbage for appropriate field trial data), incorporating %CT as residue adjustment factor (i.e., multiplying by %CT) and correct for PF; use 1/2 LOD for non-detects. The result should be entered into the exposure analysis as a point estimate. The tolerance-level residue value should be used in the absence of average field trial data.

- or -

- use monitoring data for the raw agricultural commodity (RAC), corn in this case, incorporating 1/2 LOD and %CT to calculate the average residue; multiply the average RAC residue by the PF and incorporate the resulting value as a point estimate in the MC analysis.

The reference for a PF of 0.14 for corn starch and justification for its use for corn sugar and corn sugar molasses should be cited.

Sorghum - Field trial data (10 data points, both dimethoate and omethoate below detection limit of 0.01 ppm in all data) and 1% CT were used to generate the RDF for sorghum (including milo), with the DEEM default PF of 1.

EPA Response:

The procedure is not acceptable since sorghum is considered to be a blended commodity. Appropriate procedures for blended commodities were discussed above (see field corn). However, because of the low values for sorghum, it is unlikely to see a substantial difference, if any, in the outcome of the assessment by using this procedure.

Wheat - Composite PDP monitoring data for wheat grain (1995-1996, 940 samples, zero detects) were used. However, since no detects were found, data could not be imputed because no standard deviation could be generated. Therefore, the average limit of detection (LOD) of 0.01 was used in the RDF and adjusted for 1% CT (by adding zeroes for % non-treated). The RDF (residue data file) was used for wheat bran, wheat flour, wheat germ, wheat germ oil, and wheat rough. No processing factor was used since no detectable residues were found in the processing studies.

EPA Response:

The procedure is not acceptable. Appropriate procedures for blended (wheat grain) and blended processed commodities (wheat bran, wheat flour, wheat germ, wheat germ oil, wheat rough) were discussed above (see field corn). In addition, the most recent BEAD report indicates 7.6% CT for wheat.

Citrus Fruits

Grapefruit - The grapefruit tolerance of 2 ppm and 10% CT was used. The residue data file (RDF) was applied to grapefruit juice, grapefruit juice concentrate, grapefruit peel, and grapefruit-peeled fruit. The processing factors used were 0.15 for grapefruit juice, 0.59 for grapefruit juice concentrate, and the DEEM default PF of 1 for grapefruit peel and grapefruit-peeled fruit.

EPA Response:

The procedure was not acceptable for grapefruit juice or grapefruit juice concentrate, since these commodities are considered processed blended commodities. Appropriate procedures for blended processed commodities were discussed earlier (see field corn blended processed food forms). The most recent BEAD report indicates 8.5% CT for grapefruit. The Agency concurs with using the tolerance value for grapefruit, grapefruit peel, and grapefruit-peeled rather than the old field trial data as discussed earlier (see comments for cabbage). The Agency also concurs with using the DEEM default PFs in the absence of appropriate processing studies. The PFs used for grapefruit juice, grapefruit juice concentrate are calculated values (see the last page) and acceptable. The procedure used for grapefruit peel and grapefruit-peeled fruit is acceptable.

Oranges - The registrant imputed PDP data (1994-1996, 1892 samples, 22 detects, min = 0.006 ppm and max = 0.036 ppm) for use in the analysis. A total of 168 data points were added at 0.0115 ppm (1/2 LOD dimethoate + 1/2 LOD omethoate) to match the 10% CT. The RDF was applied to orange juice, raw (PF of 0.15), orange peel, and orange-peeled fruit.

EPA Response:

The procedure used by the registrant was not acceptable. Using PDP monitoring data for non-blended commodities in acute dietary risk assessment (orange and orange juice) is not currently an approved practice; therefore in the absence of field trial data for a commodity, tolerance values should be used.

Orange Juice - Composite PDP data for orange with 10% CT were used. The RDF was applied to orange juice, canned-cooked (PF of 0.15), orange juice, frozen-raw (PF of 0.15), and orange juice concentrate (PF of 0.56).

EPA Response:

The procedure used by the registrant was not acceptable. Orange juice and orange juice concentrate are considered to be non-blended commodities; appropriate field trial data (see comments for cabbage) or tolerance-level residue should be used.

Lemons - Imputed PDP data for oranges were translated to lemons with 35% CT (lemon % CT). 641 data points were added at 0.0115 ppm (1/2 LOD dimethoate + 1/2 LOD omethoate) to match the 35%CT. The RDF was applied to lemon peel and peeled lemons.

EPA Response:

The procedure used by the registrant was not acceptable. Using PDP monitoring data for non-blended commodities in acute dietary risk assessment is not currently an approved practice; therefore in the absence of field trial data for a commodity, tolerance-level residues should be used. In addition, the most recent BEAD report indicates 58.4% CT for lemons.

Lemon Juice - Composite PDP data for oranges were translated to lemons with 35% CT (lemon % CT). The RDF was applied to lemon juice (PF of 0.15) and lemon juice concentrate (PF of 0.86).

EPA Response:

The procedure is not acceptable since lemon juice and lemon juice concentrate are considered to be blended processed commodities. Appropriate procedures for blended processed commodities (lemon juice and lemon juice concentrate) were discussed earlier (see field corn blended processed food forms). In addition, the most recent BEAD report indicates 58.4% CT for lemons.

Tangerines - A tolerance of 2 ppm and 10% CT (taken from orange %CT) was used (no PDP data available). The RDF was applied to tangelos, tangerines, tangerine juice (PF of 0.15), and tangerine juice concentrate (PF of 0.48).

EPA Response:

The procedure is not acceptable for tangerine juice and tangerine juice concentrate since they are considered blended processed commodities. Appropriate procedures for blended processed commodities (tangerine juice and tangerine juice concentrate) were discussed earlier (see field corn blended processed food forms). The most recent BEAD report indicates 21.9% CT for tangerines.

Cucurbits

Melons - The melon tolerance of 1 ppm was used for cantaloupes (including nectar and pulp), casabas (including casabas, crenshaws, honeydew melons, and persian melons), and watermelon (including watermelon and watermelon juice). Furthermore, 10% CT for cantaloupe and

watermelon, and 40% CT (% CT for melons-honeydew) for casabas were applied. The DEEM default PFs of 1 were used for all the processed commodities.

EPA Response:

The procedure is not acceptable for watermelon juice and cantaloupe nectar, blended processed commodities. Appropriate procedures for blended processed commodities were discussed earlier (see field corn blended processed food forms). In addition, the most recent BEAD report indicates 12.7% CT for cantaloupes, 18.3% CT for melons, 48.8% CT for melons (honeydew), and 8.2% CT for watermelon.

Fruiting Vegetables

Sweet Peppers - The tolerance of 2 ppm and 30% CT values were used. The RDF was applied to peppers-sweet-garden, pimientos, and peppers-others.

EPA Response:

The most recent BEAD report indicates 47.3 % CT for sweet peppers which should be incorporated in the analysis. The Agency concurs with using the tolerance rather than residue from the old field trial data as discussed earlier (see comments for cabbage).

Hot Peppers - The tolerance of 2 ppm and a 4% CT value were used. The RDF was applied to chili peppers (jalpeno).

EPA Response:

The most recent BEAD report indicates 10.4 % CT for hot peppers. The Agency concurs with using the tolerance value rather than the old field trial data as discussed earlier (see comments for cabbage).

Tomatoes, Fresh- Imputed PDP data (1996, 174 samples, 7 detects, min = 0.009 ppm, max = 0.033 ppm) were used. A total of 11 data points were added at 0.013 ppm (1/2 LOD dimethoate + 1/2 LOD omethoate) to match the 10% CT. The RDF was applied to tomatoes-whole and tomatoes-dried with the DEEM PFs of 1 and 14.3 respectively.

EPA Response:

The procedure used by the registrant is not acceptable. Using PDP monitoring data for non-blended commodities in acute dietary risk assessment is not currently an approved practice; therefore in the absence of field trial data for a commodity, tolerance-level residues should be used. In addition, the most recent BEAD report indicates 18.3 % CT

for fresh tomatoes.

Tomatoes, Processed - Composite PDP data for tomatoes with 10% CT value were used. The PFs of 1.62 for catsup, 0.11 for tomato juice, 2.62 for tomato paste, and 1.53 for tomato puree were applied.

EPA Response:

The procedure is not acceptable since processed tomato commodities are considered to be blended. Appropriate procedures for blended processed commodities were discussed earlier (see field corn blended processed food forms). The PFs used by the registrant are acceptable. In addition, the most recent BEAD report indicates 60% CT for processed tomatoes.

Legume Vegetables

Peas (succulent) - Field trial data were used (8 samples, 0.25-0.53 ppm for combined dimethoate and omethoate, with preharvest interval of zero days, and 20% CT). The residue data file was applied to garden, green, succulent / blackeye / cowpeas (cowpeas was claimed earlier in the submitted report as a crop not supported by Cheminova). The DEEM default PF of 1 was used for all.

EPA Response:

In the next DEEM analysis, the most recent BEAD values for % CT should be used (56.8% CT for green peas, and 29.5% CT for green processed peas).

Peas (dry) - The tolerance of 2 ppm and 5% CT value were used.

EPA Response:

The Agency concurs with using the tolerance rather than residues from the old field trial data as discussed earlier (see comments for cabbage). In the next DEEM analysis, the most recent BEAD values for % CT should be used (8.4% dry peas).

Succulent Beans - Imputed PDP data (1994-1995, 1178 samples, 75 detects, min = 0.0065 ppm and max = 1.08 ppm) for fresh green beans were used. A total of 102 data points were added at 0.0095 ppm (1/2 LOD dimethoate + 1/2 LOD omethoate) to match the 15%CT. The RDF was applied to the following beans: broad, green, hyacinth, other, yellow/wax, and mung bean (sprouts) with a DEEM default PF of 1 for all.

EPA Response:

The procedure is not acceptable. Using PDP monitoring data for non-blended commodities in acute dietary risk assessment is not currently an approved practice; therefore in the absence of field trial data for a commodity, tolerance values should be used³. The most recent BEAD report indicates 19.6 % CT for green beans and 14.9% CT for fresh snap beans. Contrary to the statement in Table 3 of Cheminova's report, the imputed PDP data for fresh green beans *were* also used for other beans instead of their tolerance values.

Beans (dry) - The tolerance of 2 ppm and a 5% CT value were used³. The RDF was applied to blackeye peas / cowpeas (cowpeas was claimed earlier in the submitted report as a crop not supported by Cheminova), broad, garbanzo / chick pea, great northern, hyacinth, kidney, lima, navy, other, pigeon beans, and pinto beans.

EPA Response:

The procedure is not acceptable since dry beans are considered to be blended commodities. Appropriate procedures for blended commodities were discussed earlier (see field corn). In addition, the adequacy of the tolerances for beans, dried and succulent can not be ascertained until the registrant clarifies the maximum use rate they wish to support on beans. The most recent BEAD report indicates 7.0 % CT for dry beans.

Lentils⁴ - The lentil tolerance of 2 ppm and a 20% CT (for green peas) value were used. The RDF was applied to lentils, split and lentils, whole with the DEEM default PF 1.

EPA Response:

The Agency concurs with using the tolerance rather than residues from the old field trial data as discussed earlier (see comments for cabbage). However, the most recent BEAD report indicates 56.8% CT for green peas.

Soybeans - The tolerance of 0.05 ppm and a 1% CT value were used for soybean flours (defatted, full fat, and low fat), mature seeds (dry), soybean oil, sprouted seeds, and unspecified. The DEEM default PF of 0.33 was used for sprouted seed, and a default PF of 1 was applied to the rest.

EPA Response:

³ No additional field trial data are required to support the use of dimethoate on beans, dry and succulent. The currently established tolerance for residues of dimethoate in/on beans will be reassessed once the registrant clarifies the maximum use rate they wish to support on beans.

⁴ The tolerance for lentils is revoked. The established tolerance for peas applies to lentils.

The procedure is not acceptable since soybean, soybean oil, and sprouted seeds are considered blended processed commodities. Appropriate procedures for blended and blended processed commodities were discussed earlier (see field corn).

Leafy Vegetables

Celery - The PDP monitoring data for celery contained no detects. Therefore, composite PDP data (1994, 176 samples, zero detects), using 1/2 LOD values were used. An additional 9 data points were added at 0.0105 ppm (1/2 LOD dimethoate + 1/2 LOD omethoate) to match the 5%CT. The RDF was applied to celery and celery juice with the DEEM default PF of 1 for both.

EPA Response:

The procedure is not acceptable since celery is a non-blended commodity and celery juice is considered a blended processed commodity. Using PDP monitoring data for non-blended commodities in acute dietary risk assessments is not currently an approved practice; therefore in the absence of field trial data for a commodity, tolerance value for celery should be used. Appropriate procedures for blended processed commodities (celery juice) were discussed earlier (see field corn food forms). In addition, since there is no BEAD value for % CT for celery, the justification for using 5% CT for celery should be submitted.

Endive (escarole) / lettuce - Imputed PDP data for lettuce (1994, 691 samples, 85 detects with min = 0.0045 and max = 1.4 ppm) were used. An additional 330 data points were added at 0.012 ppm (1/2 LOD dimethoate + 1/2 LOD omethoate) to match the 60%CT. The RDF was applied to endive - curly and escarole, lettuce - head, lettuce - leafy, lettuce- unspecified with default PF of 1 for all.

EPA Response:

The procedure is not acceptable since all the commodities the RDF was applied to are considered to be non-blended. Using PDP monitoring data for non-blended commodities in acute dietary risk assessments is not currently an approved practice; therefore in the absence of field trial data for a commodity, tolerance-level residues should be used. The most recent BEAD report indicates 52.1 % CT for lettuce, 58.5% for head lettuce, 42.4% for lettuce - other.

Head Lettuce - Imputed PDP data for lettuce (1994, 691 samples, 85 detects with min = 0.0045 and max = 1.4 ppm) were used. An additional 330 data points were added at 0.012 ppm (1/2 LOD dimethoate + 1/2 LOD omethoate) to match the 60%CT.

EPA Response:

The procedure is not acceptable as explained for endive.

Leaf Lettuce - Imputed PDP data for spinach (1995-1996, 1126 samples, 172 detects with min = 0.008 and max = 11 ppm) were used. No data points were added to match the 5% CT since the number of actual detects (172) exceeded the number of expected detects (57).

EPA Response:

The procedure is not acceptable since leaf lettuce is considered a non-blended commodity. Using PDP monitoring data for non-blended commodities in acute dietary risk assessment is not currently an approved practice; in the absence of field trial data for a commodity, tolerance values should be used. In addition, the most recent BEAD report indicates 52.1 % CT for lettuce.

Spinach and Swiss Chard - Imputed PDP data for spinach (1995-1996, 1126 samples, 172 detects with min = 0.008 and max = 11 ppm) were used. No data points were added to match the 5%CT since the number of actual detects (172) exceeded the number of expected detects (57). The default PF of 1 was used for both commodities.

EPA Response:

The procedure is not acceptable since spinach and swiss chard are considered to be non-blended commodities. Using PDP monitoring data for non-blended commodities in acute dietary risk assessments is not currently an approved practice; therefore in the absence of field trial data for a commodity, tolerance values should be used. In addition, the most recent BEAD report indicates 17.2 % CT for spinach.

Pome Fruits

Apples - Imputed PDP data for apples (1994-1996, 1910 samples, 130 detects with min = 0.005 and max = 0.538 ppm) were used. An additional 539 data points were added at 0.012 ppm (1/2 LOD dimethoate + 1/2 LOD omethoate) to match the 35%CT. The RDF was applied to apples (with PF of 1) and apples-dried (default PF of 8).

EPA Response:

The procedure is not acceptable since apple is considered to be a non-blended commodity. Using PDP monitoring data for non-blended commodities in acute dietary risk assessments is not currently an approved practice; therefore in the absence of field trial data for a commodity, tolerance values should be used. In addition, the most recent BEAD report indicates 14.9 % CT for apples.

Apple Juice/Cider/Concentrate - Composite PDP data for apples (1994-1996, 1910 samples,

130 detects with min = 0.005 and max = 0.538 ppm) were used. An additional 539 data points were added at 0.012 ppm (1/2 LOD dimethoate + 1/2 LOD omethoate) to match the 35% CT. The RDF was applied to apple juice/cider and apple juice/concentrate with default PFs of 1.3 and 3.9 respectively.

EPA Response:

The procedure is not acceptable since apple juice/cider/concentrate are considered blended processed commodities. Appropriate procedures for blended processed commodities were discussed earlier (see field corn blended processed food forms). In addition, the most recent BEAD report indicates 14.9 % CT for apples which should be used in any future analysis.

Pears - Imputed PDP data for apples were translated to pears, with 10% CT (pears %CT). The RDF was applied to pears (with the DEEM default PF of 1) and pears-dried (with the DEEM default PF of 6.25).

EPA Response:

The procedure is not acceptable since pear is considered to be a non-blended commodity. Using PDP monitoring data for non-blended commodities in acute dietary risk assessments is not currently an approved practice; therefore in the absence of field trial data for a commodity, tolerance values should be used. The most recent BEAD report indicates 5.6 % CT for apples.

Root and Tuber Vegetables

Potatoes - Imputed PDP data for potatoes (1995-1996, 1401 samples, 1 detect) were used. An additional 42 data points were added at 0.007 ppm (1/2 LOD dimethoate + 1/2 LOD omethoate) to match the 3%CT. The RDF was applied to Potatoes-dry, potatoes-peel, potatoes-peeled, potatoes-unspecified and potatoes-whole (all being white potatoes). The PF of 0.184 (taken from potato granules) was used for potatoes-dry; the DEEM default PF of 1 was used for the rest.

EPA Response:

The procedure is not acceptable since all potato food forms except dry potatoes are considered to be non-blended commodities. Using PDP monitoring data for non-blended commodities in acute dietary risk assessments is not currently an approved practice; therefore in the absence of field trial data for a commodity, tolerance values should be used. In addition, reference and explanation for using the PF of 0.184 for potato granules should be submitted. For dry potatoes, the appropriate procedure for blended processed commodities should be followed (see field corn blended processed food forms). The

most recent BEAD report indicates 3.5 % CT for potatoes.

Turnips - Tolerances of 0.2 ppm and 2 ppm were used for roots and tops respectively. An assumption of 100% CT and a default PF of 1 was used in both cases.

EPA Response:

The procedure is acceptable. The Agency concurs with using the tolerance rather than residues from the old field trial data as discussed earlier (see comments for cabbage). In addition, the reassessed tolerance for turnip roots is 0.02 ppm.

Small Fruits and Berries

Blueberries - The tolerance of 1 ppm (import tolerance) and 85% CT (based on %import from Canada) were used. There are no U. S. registrations as of August 16, 1995.

EPA Response:

The procedure is acceptable.

Grapes - Imputed PDP data for grapes (1995-1996, 1883 samples, 300 detect with min = 0.006 and max = 1.47 ppm) were used. No data points were added to match the 10%CT since the number of actual detects (300) exceeded the number of expected detects (189). The RDF was applied to grapes, grapes-leaves, grapes-raisins with the DEEM default PF of 1 applied to all.

EPA Response:

The procedure is not acceptable since grapes, grapes-leaves and grapes-raisins are considered to be non-blended commodities. Using PDP monitoring data for non-blended commodities in acute dietary risk assessments of is not currently an approved practice; therefore in the absence of field trial data for a commodity, tolerance values should be used. In addition, the most recent BEAD report indicates 13.0 % CT for grapes. Furthermore, the DEEM default PF for grapes-raisins is 4.3 instead of 1.

Grape Juice - Composite grape PDP data (for grapes, above) were used with 10% CT. The RDF was applied to grape juice (with a default PF of 1.2), grape juice concentrate (the DEEM default PF of 3.6), and grapes-wine and sherry (with the DEEM default PF of 1).

EPA Response:

The procedure is not acceptable since grape juice, juice concentrate, wine and sherry are considered to be processed blended commodities. Appropriate procedures for blended

processed commodities were discussed earlier (see field corn blended processed food forms). In addition, the most recent BEAD report indicates 13.0 % CT for grapes and 11.4% CT for grapes-wine.

Stone Fruits

Cherries - The tolerance of 2 ppm and 10%CT (BEAD 1998 value is 8.7%) were used. The RDF was applied to cherries, cherries-dried (with default PF of 4), and cherries-juice (with default PF of 1.5).

EPA Response:

The procedure is not acceptable for cherry juice since it is a blended commodity. Appropriate procedures for blended processed commodities were discussed earlier (see field corn blended processed food forms). The most recent BEAD report indicates 8.7% CT for cherries, 14.0% for sweet cherries and 5.4% for tart cherries.

Tree Nuts

Pecan - The tolerance of 0.1 ppm and 20% CT value were used. The RDF was applied only to pecans (with the DEEM default PF of 1).

EPA Response:

The procedure is acceptable. The Agency concurs with using the tolerance rather than residues from the old field trial data as discussed earlier (see comments for cabbage).

Other Crops

Cottonseed- The tolerance of 0.1 ppm and 10%CT were used. The RDF was applied to cottonseed meal (with calculated PF of 1.33) and cottonseed oil (with calculated PF of 0.33). .

EPA Response:

The procedure is not acceptable since cottonseed meal and oil are blended processed commodities. Appropriate procedures for blended processed commodities were discussed earlier (see field corn blended processed food forms). The PF used for cottonseed oil is incorrect: the appropriate PFs (Bonnie Cropp-Kohlligian, DP Barcode: D206804, 2/15/96) for crude oil, refined oil, bleached/deodorized oil are 0.9, 0.6, and 0.6, respectively.

Safflower - The tolerance of 0.1 ppm and 25%CT were used. The RDF was applied to safflower

oil and safflower seed with using a default PF of 1 for both (safflower processing data are outstanding; see RED).

EPA Response:

The procedure is not acceptable since safflower oil is a blended processed commodity. Appropriate procedures for blended processed commodities were discussed earlier (see field corn blended processed food forms). The Agency concurs with using the tolerance rather than residues from the old field trial data for safflower seed as discussed earlier (see comments for cabbage). The most recent BEAD report indicates 41.1% CT for safflower.

Livestock Commodities

Beef / Goat / Horse / Sheep / Veal - The tolerance values of 0.02 ppm and 100%CT were used for fat, MBYP, kidney, organs, meat, beef-dried and veal-dried. The PFs of 1.92 was used for beef-dried and veal-dried.

Milk - The tolerance of 0.002 ppm and 100%CT were used.⁵

Pork - The tolerance of 0.02 ppm (for hog fat, MBYP, and meat) and 100% CT were used. The tolerance was applied to pork MBYP, pork fat, pork lean, pork kidney, pork liver, pork-organ meats (other).

Eggs - The existing egg tolerance of 0.02 ppm and 100%CT were used.

Processing Factors

Citrus Juice concentrates - All the processing factors for citrus juice concentrates were calculated by multiplying the calculated processing factor for orange juice by the ratio of the default juice concentrate and default single-strength juice processing factors for each citrus juice. For example, in the case of orange juice concentrate, 0.15 (the calculated processing factor for orange juice) was multiplied by the ratio of 6.7 (the default orange juice concentrate processing factor) and 1.8 (the default single-strength orange juice processing factor). This results in a corresponding orange juice concentrate processing factor of 0.56 (0.15×3.72), where $3.72 = 6.7 / 1.8$). The same procedure was applied to grapefruit, lemon, and tangerine juice concentrates.

Other commodities - The established processing factors or the DEEM default processing factors were used.

⁵ Once outstanding metabolism data are submitted, the available magnitude of the residue data for milk will be reevaluated and tolerance revisions may be required (D215029, CBTS No. 15499, G. Kramer, 5/9/95).

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